510(k) Summary
K102619

MAY 13 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date prepared: June. 20, 2010

1. Company and Correspondent making the submission:
   Name – 3D Imaging & Simulations Corp.
   Address – 815, Tamnip-Dong, Yuseong-Gu, Daejeon, Korea
   Telephone – +82-42-931-2100
   Fax – +82-42-931-2299
   Contact – Jiin Jung / Vice President
   E-mail – jiinjung@3-disc.com

2. Device :
   Trade/proprietary name : FireCR
   Common Name : Computed Radiography Scanner
   Classification Name : Solid-State X-ray Imaging system

3. Predicate Devices :
   Manufacturer : AGFA Corporation
   Device : ADC Compact Plus
   510(k) Number : K013138(Decision Date - Sep. 28. 2001)

4. Classifications Names & Citations :
   21CFR 892.1650, MQB - Solid-State X-ray Imaging system, Class 2

5. Description :

5.1 General

The FireCR is Computed Radiography System which produces the X-ray diagnostic image in digital format instead of using traditional screens and film. This device utilizes reusable X-ray storage phosphor plate (IP) that is sensitive to X-ray and stores latent image when it is exposed to X-ray. After X-ray exposure to the X-ray storage phosphor plate, X-ray storage phosphor plate is scanned by means of laser in the device. Latent image in the X-ray storage phosphor plate is released in a form of light by laser scanning. Then the light is collect and converted into a form of digital image. The signal processing is made to the digital image data such as the digital filtering, the gain & offset correction and flat fielding. The image can then be viewed on a computer workstation, adjusted if necessary, then stored locally, sent to an archive, printed or sent to PACS system. After acquisition of latent image from the X-ray storage phosphor plate, it is erased thoroughly to be reused.

5.2 Main Features

Scanning Mechanism

FireCR employs a scanning mechanism using swing mirror to construct its compact and rigid structure.

High Throughput

Its unique and patented dual direction scanning mechanism enables to improve the efficiency and high throughput.

Scanning Resolution

User selectable resolution of 100μm and 200μm allows user to make diagnosis on variable purposes.

Detector

High sensitive photomultiplier tube equipped in ***FireCR*** delivers high gain, wide dynamic range and high speed response for radiographic imaging.

Powerful Acquisition and Diagnostic Software

QuantorMed Acquisition and Diagnostic Software is supplied with every ***FireCR***, and its accurate and rapid data processing make the scanner more powerful.

5.3 Product features

- Photomultiplier Tube :(PMT)
- 14" x17" imaging area.
- Wide dynamic range with 16-bit digitization
- Image process parameters are selectable according to the body part to make best images for diagnosis
- DICOM3.0 standard compliance
- Image Format : 3500 x 4300
- User Selectable Scanning Resolution : 100um and 200um

6. Indications for use :

This device is a Computed Radiography Scanner and intended for use in producing digital X-Ray images for general radiography purposes. It comprises of scanner, cassette with reusable imaging plate and workstation software. It scans X-Ray exposed image plate and produces X-Ray image in digital form. Then, digital image is transferred to workstation for further processing and routing. This device is intended to be operated in a radiological environment by qualified staff. This device is not approved for the acquisition of mammographic image data.

7. Comparison with predicate device :

3D Imaging & Simulations Corp. believes that the Computed Radiography Scanner (FireCR) is substantially equivalent to ADC Compact Plus of AGFA Corporation.

8. Safety, EMC, Biocompatibility and Performance Data :

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2(2001).

Non-clinical & Clinical considerations according to FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices" was performed.

All test results were satisfactory.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification 3D Imaging & Simulations Corp. concludes that the Digital Radiography System(FireCR) is safe and effective and substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

3DISC Americas
% Mr. Daniel Kamm, P.E.
Submission Correspondent
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

AUG 23 2013

Re: K102619
Trade/Device Name: Computed Radiography Scanner/FireCR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: March 1, 2011
Received: March 3, 2011

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of May 13, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K10

Device Name: Computed Radiography Scanner / FireCR

Indications for Use:

This device is a Computed Radiography System and intended for use in producing digital X-Ray images for general radiography purposes. It comprises of scanner, cassette with reusable phosphor storage plate (IP) and workstation software. It scans X-Ray exposed image plate and produces X-Ray image in digital form. Then, digital image is transferred to workstation for further processing and routing. This device is intended to be operated in a radiological environment by qualified staff.

This device is not intended for the acquisition of mammographic image data.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K102619

DEPARTMENT OF HEALTH & HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Date: August 15, 2012

From: William C. Jung

To: The Record

Subject: Reassignment of Regulation Number for MQB

510(k) K102619, Computed Radiography Scanner/FireCR was originally assigned a Product Code of MQB (solid state x-ray imager (flat panel/digital imager) under regulation number, 21 CFR 892.1650, image-intensified fluoroscopic x-ray system. The Product Code MQB is being reassigned under 21 CFR 892.1680.